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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAIDHA, TEKCHAND	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,946	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-59 and 74-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-59 and 74-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Final Rejection

1. Applicants' amendment and arguments filed on May 25, 2005 is acknowledged.

2. Declaration of Merry R. Sherman Under 37 C.F.R. 1.132, filed on May 25, 2005 is also acknowledged.

3. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

4. Claims 50-59 & 74-76 drawn to an isolated tetrameric mammalian uricase are pending and under consideration in this Office Action.

5. Applicants' representative Brian J. Del Buono's interview with the Examiner o April 21, 2005, is acknowledged. As indicated by the Applicants' representative, during the interview, the claims, cited art and the Office Action were discussed. During the interview the Examiner indicated considering data relevant to the outstanding rejections. Suitable amendment to the claims clearly distinguishing the claimed invention over the prior art cited will also considered.

6. Applicants' response and Declaration of Merry R. Sherman filed May 25, 2005 have been fully considered but they are not deemed to be persuasive as explained below.

7. New matter added only to the claims – rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-59 & 74-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. Claim 50, recite new matter as follows: 'and less than about 10% of said uricase is in a non-tetrameric aggregated form.' Claims 51-59 & 74-76 depend upon claim 50 and includes the added new matter.

Applicants', support for amendments to the claims to be found (*see* page 6 of Applicants response, filed, May 25, 2005) in the instant specification at page 17, lines 3-5. However, the specification at page 17, lines 3-5, does not contain the recited language claimed. Specification, on page 17, lines 3-5, recite "Of the uricase thus pooled, at least 90% may be in tetrameric form; the undesirable aggregates may thus constitute as little as about 10%, 5%, 2% or less of the total isolated uricase". This is not the same as claimed.

Furthermore, no were in the specification can the combination of ..."at least about 90%" ..and ... "at less than about 10% ...", as recited in claim 50, can be found.

8. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-53 are rejected under 35 U.S.C. 102(b) as anticipated by Lee et al. [Science 239, 1288-1291 (1988), IDS, previously cited].

Lee et al. (1988) teach the recombinant production of full length amino acid sequence of porcine Urate oxidase (uricase) which is tetrameric and is substantially pure. Mammalian uricase is disclosed as a tetramer with subunit size of 32,000 daltons (page 1288, column 2,first paragraph after the abstract). The reference further teaches purification to **homogeneity** of Porcine and murine urate oxidase (see, page 1289, second column). Oxidation of uric acid

to allantoin is catalyzed by urate oxidase (see abstract). Increased uric acid level, due to lack of this enzyme in man can lead to gouty arthritis (page 1288, column 2).

Applicants' claims are directed to 'tetrameric mammalian uricase, wherein at least about 90% is in tetrameric form'. This is interpreted here to mean that more than 90% may also be present in the tetrameric form. More than 90% may also mean 100% or homogenous preparation. Therefore, the homogenous preparations of porcine or murine tetrameric uricase comprises the at least about 90% tetrameric form of mammalian uricase claimed. The reference therefore anticipates the claims.

Applicants' arguments:

As far as the rejection is concerned the Applicants find the anticipation rejection legally and factually baseless. Citing MPEP § 707.07(f) (February 2003), argue that where the Applicants traverse any rejection, the examiner should, if he or she repeats the rejection, take note of Applicants arguments and answer the substance of it. Based solely on this reason, Applicants respectfully contend that the present anticipation rejection under 35 U.S.C. 102(b) is improper, and should be withdrawn.

Applicants are reminded that the basis of traversal be found in the art applied. Regarding the Applicants arguments being not addressed, it is unclear what arguments are being referred to, which were not addressed. Further, it is not important to address every point which does not have a bearing to advancing prosecution, and/or points already explained in the art rejection.

Applicants in explaining Lee et al., point that Examiner contends that Lee discloses the recombinant production of full length amino acid sequence of porcine Urate oxidase (uricase) which is tetrameric and is substantially pure. Mammalian uricase is disclosed as a tetramer with subunit size of 32,000 daltons (page 1288, column 2,first paragraph after the abstract). The reference further teaches purification to **homogeneity** of Porcine and murine urate

oxidase (see, page 1289, second column). Applicant respectfully disagrees with this interpretation for the following reasons.

Lee does not expressly disclose the purification of tetrameric mammalian uricase as recited by the claim of the present application. This reference only indicates *in passing* that the porcine liver and murine urate oxidase were purified to homogeneity. The reference does not indicate that at least 90% of the purified uricase was in tetrameric form. Indeed, the reference does not indicate in what form the purified uricase was, let alone that at least about 90% of it was in a tetrameric form.

From the article [Lee et al.] and from the clear explanation, it is amply clear that the art as applied anticipates the claims. First of all, the art cited clearly points to the fact that the mammalian uricase is disclosed as a tetramer with subunit size of 32,000 daltons (page 1288, column 2,first paragraph after the abstract). This is also well documented in Applicants' own specification on page 3, line 15, citing Wu et al. [PNAS USA 86: 9412-9416, 1989].

Regarding Applicants' arguments that Lee's reference only indicates *in passing* that the porcine liver and murine urate oxidase were purified to homogeneity is without basis, and is distorting the facts presented in a well known and reputed scientific journal such as 'Science'. Further, as explained in the 102 rejection, at least 90% of the uricase was in tetrameric form, is encompassed by the homogeneous preparation, and is no different than what is claimed.

Applicants citing Conley et al. [Preparative Biochemistry 9:197-203 (1979)] argue that Conley report that the 'enzyme is homogeneous upon polyacrylamide gel electrophoresis in the presence of Sodium dodecyl sulfate [see Conley at p. 201]. Applicants further argue that one of ordinary skill in the art would immediately recognize, the conditions of SDS/PAGE employed by Conley (and therefore Lee) dissociate any uricase tetramer that might be present into the smaller 32-33 kDa monomeric subunits. As disclosed in the

present specification at page 16, lines 5-7, tetrameric uricase is 140 kDa protein. Hence, Conley (and therefore Lee) clearly is identifying monomeric forms of uricase, rather than tetrameric forms of uricase.

Applicants' explanation is not found persuasive because – in a denaturing gel such as SDS/PAGE, only the subunit form of the uricase is evident. Since all the 4-subunits are of the same size, the uricase appears/migrate as a single band on a SDS/PAGE. Since each subunit is approximately 32-33kDa, the native tetrameric form of the uricase in question would be 33X4=132 kDa, which is good estimate for molecular weight determination, and is within a reasonable range to that disclosed by the Applicants. Therefore, the homogeneous preparation of Lee et al. is not distinct to that claimed by the Applicants. No inherency argument is deemed necessary, because Conley's work further support Examiner's use of Lee et al. in 102 rejection.

Applicants' attention is also drawn to Conley et al. [Biochem. J (1980) 187, 727-732, IDS], at page 727, column 1, lines 1-3, where Uricase from pig liver consists of four apparently identical subunits. Table 2. further teaches the physical properties of pig uricase and define the molecular weight to be 125,000, with the subunit size of 32,000. Four identical subunits as defined by the Conley reference (1980) will further clarify that the uricase is tetrameric [four subunits].

Declaration of Merry R. Sherman Under 37 C.F.R. 1.132 (Arguments)

Applicants' support their conclusion by the data presented in the "Declaration of Merry R. Sherman Under 37 C.F.R. 1.132", and argue that these data clearly show that isolated preparations of natural and recombinant uricase, such as those prepared by the methods of Lee, contain multiple forms of the uricase, including octomers and larger aggregates. Applicants further argue that as 'shown in Figures 1 & 2 (top panel) of the Sherman declaration,

the octomers and larger aggregates (or non-tetrameric) account for greater than about 10% of the uricase present in these preparations.

This is contrary to Applicants' language in claim 50 (as amended), wherein the claim recites 'less than about 10%..in non-tetrameric form' (*see* Applicants' response, page 8, lines 10-18). This is further complicated by Applicants statement in the preceding paragraph (*see* Applicants' response, page 8, lines 3-9), wherein the non-tetrameric aggregated form of the enzyme present in such 'purified' preparations varies from more than 10% to about 80%. Therefore, base upon the diverse range of aggregations as a result of mammalian uricase purification, reported in the instant specification, the declaration of Merry R. Sherman and those claimed, it is quite clear that there is enormous variations in the composition of uricase purified depending upon perhaps the buffers, dilutions, source and so on, and that the aggregation is the inherent property of the enzyme or that the different forms of the uricase (tetrameric or non-tetrameric) may aggregate differently. Therefore the added limitation of 'less than about 10% of said uricase is in a non-tetrameric aggregated form' is neither well supported nor carry weight to the patentability of the claims. The rejection under 35 U.S.C. 102(b) is therefore maintained.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. as applied to claims 50-51 above, and further in view of Caput et al. [USP 5,382,518, January 17, 1995].

The teachings of Lee et al. are described above. Lee et al. do not teach a pharmaceutical composition for lowering uric acid levels, but teach that increased uric acid level, due to lack of this enzyme in man can lead to gouty arthritis.

Caput et al. teach purification of Urate oxidase from *Aspergillus*, an enzyme which catalyzes the degradation of uric acid to allantoin (a compound which is much more soluble than uric acid and does not crystallize at the concentrations reached in biological fluids), and therefore has therapeutic value. Pharmaceutical compositions (see column 1-2, claim 7, and the entire patent) for lowering the uric acid levels as a means for treatment of conditions associated with increased uric acid are also taught. Caput et al. do not teach mammalian uricase.

It would have been obvious for one of ordinary skill in the art to substitute Aspergillus uricase of Caput et al. with the mammalian uricase taught by Lee et al. in developing pharmaceutical compositions for lowering uric acid in body fluid of man and do so with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do so in view of the knowledge that man belongs to the class of mammals and a uricase originating from a mammalian species will be more compatible and perhaps more effective in lowering uric acid in man.

Applicants' arguments:

Applicants argue that in proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki,* 223 USPQ 785, 787-88 (Fed. Cir. 1984). In order to establish a *prima facie* case of obviousness, all of the elements of the claims must be taught or suggested by the prior art. See In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Moreover, the Examiner can satisfy the requisite burden only by showing some objective teaching in the prior art or that knowledge generally available to one of

ordinary skill in the art would lead that individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. See In re Fine, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). There is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time the invention was made. *See Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1995). lnstead, what is needed is a reason, suggestion, or motivation in the prior art that would motivate one of ordinary skill to combine the cited references, and that would also suggest a reasonable likelihood of success in making or using the claimed invention as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). In the present case, the Examiner's burden has not been satisfied.

Applicants reiterate and incorporate by reference herein the remarks made above with respect to Lee in the 102(b) rejection. Applicants continue to argue that the Lee reference does not disclose, suggest or otherwise contemplate an isolated tetrameric mammalian uricase, wherein at least about 90% is in the tetrameric form, does not teach pharmaceutical compositions comprising such uricase preparations. Therefore Lee is seriously deficient as a primary reference upon which to base a *prima facie* case of obviousness.

Applicants' arguments are considered and not found to be persuasive for the reasons extended in discussing the Lee reference with respect to 102(b) rejection in item 5.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941

(Fed. Cir. 1992). In this case, from the combined teachings of Lee et al. and Caput et al. it would have been obvious for one of ordinary skill in the art to substitute Aspergillus uricase of Caput et al. with the mammalian uricase taught by Lee et al. in developing pharmaceutical compositions for lowering uric acid in body fluid of man and do so with a reasonable expectation of success.

Applicants' arguments [pages 12-13 of their response] referring to instant specification at page 2, lines 1-7, 18-19 & 24-28, and the statements that –

(1) 'specifically, since humans do not produce uricase (see Specification at page 1, lines 24-26), uricases from any other species, including other mammals, would be recognized as foreign by the human immune system and would be rapidly cleared or, in some hypersensitive humans, may lead to anaphylactic reactions (see Specification at page 2, lines 1-7 and 24-28)'; and

(2) Second, as also pointed out in the specification, enzymes based on the deduced amino acid sequences of uricases from mammals, including pig and baboon, have been shown not to be suitable candidates for human clinical use due to problems of insolubility. Specifically, it is known that unmodified uricases obtained from mammals "are nearly insoluble in solvents that are compatible with safe administration by injection." Specification at page 2, lines 1-7 & 24-28 and US 2003/0166249 at page 1, paragraph 0004. Thus, even apart from the immunogenicity problems noted above, one of ordinary skill would not have been motivated to use uricases from other mammalian species instead of *Aspergillus* uricase due to the insolubility of these unmodified uricases at physiological pH.

Applicants arguments have been reconsidered, in the light of the reference to the published application, but not found persuasive, because one of ordinary skill in the art is also well aware of pegylating or modifying the mammalian uricase in order to overcome the problem of immunogenicity and therefore would not more likely be motivated away from using mammalian

uricase to achieve the presently claimed invention. Further, all these problems cited by the Applicants should have also led the Applicants away from preparing a uricase composition comprising unmodified or non-pegylated uricase, however, it did not. Therefore, for the same reason, one of ordinary skill would not have been motivated to use uricases from other mammalian species and do so with a reasonable expectation of success.

Are the Applicants going on the record, and stating that their claims to pharmaceutical composition (claims 74-76), which comprise the unmodified uricase will be not viable for a pharmaceutical use because of the inherent problems (problem of immunogenicity & insolubility of these unmodified uricases at physiological pH) with the mammalian uricases? If this is indeed the case, then claims 74-76, will have to be also considered under 35 U.S.C. 101 not supported by either a specific or substantial asserted utility or a well established utility. Clarification is requested.

In response to applicant's argument that there is no motivation to combine the cited references, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicants, further point that the requisite motivation must be found either in prior art or in the knowledge that is generally available to those skill in the art; a baseless assumption of such knowledge is legally impermissible under *Fine* and *Kotzhab*. In response such a motivation is clearly drawn from the teachings and the knowledge generally available to those skilled in the art. See the entire documents of the cited references.

Therefore the rejection under 35 U.S.C. 103(a) is maintained.

10. ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 50-59 & 74-76 are rejected under the judicially created doctrine of double patenting over claims 1-30 of U. S. Patent No. **6783965** since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. This is revised double patenting rejection, since the allowed claims are now patented and the Examiner has access to the patented claims, unlike the prior allowed claims. Applicants prior arguments presented are moot in view of this revised rejection. In view of this revised rejection, this office action is made non-final.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

Applicants product or composition claims to mammalian uricase in this application differ in scope to patented claims directed to mammalian uricase containing at least 20% of uricase in the tetrameric form as compared to at least 90% of uricase in tetrameric form [instant claims], the instant claims

being encompassed by the patented claims. The instant claims are a species of the patented genus claims, are therefore, anticipatory.

The rejection is maintained, since Applicants requested that this rejection b held in abeyance until subject matter that is otherwise patentable is identified.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (571) 272-0940. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group in the Technology Center is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 571 272-1600.

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